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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,946	04/19/2001	L. David Williams	2057.0090003	5256

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
01/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/839,946	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/2008 &10/23/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Rejection

1. Amendment and response to Non-Final Office Action filed 10/23/2008 is acknowledged.

2. Claims 50-61 are pending and under consideration.

3. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn. The reasons are discussed following the rejection(s).

4. **New Matter added to claims** - [New Matter rejection]

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), **at the time the application was filed**, had possession of the claimed invention. Applicant's addition [new matter] of 'greater than 90%' in claim 50 is not supported by the original disclosure. Applicants are required to cancel the new matter in reply to this office action. The original claims and the original specification provide no basis for:

1. "greater than 90% of said uricase in tetrameric form (claim 50).
2. "at least 95% of said uricase in tertrameric form (claim 60).
3. "at least 98% of said uricase in tertrameric form (claim 61).

Claims 51-59 are included in the rejection for not correcting the defect present in the base claim(s).

Citing In re Wertheim, Applicants argue that "the court held that a disclosure of "25-60% solid content" was adequate written description for a claim to a solid content of "between 35%-60%" although the narrower latter range was not expressly disclosed in

the application. See Wertheim at 265 (finding that there was no evidence of any distinction in terms of the operability of appellants' process or of the achieving of any desired result between the broad range disclosed in the specification and the narrower claimed range). In addition, in *In re Blaser*, the court held that the appellant's disclosure of heating a reaction to between 60-200 C in their specification was adequate support for the claimed range of 80-200 C that is encompassed within the explicitly disclosed range of 60-200 C. *In re Blaser*, 556 F.2d 534, 538 (CCPA 1977).

Similarly, the present specification discloses that "at least 90% [of the uricase] may be in the tetrameric form; the undesirable aggregates may thus constitute as little as about 10%, 5%, 2%, or less, of the total isolated uricase." See specification at page 17, lines 3-5. Thus, the specification clearly discloses compositions in which the proportion of tetrameric uricase present in the composition ranges from at least 90% to 100% (since the total tetrameric uricase can not exceed 100%). Claim 50 is drawn to tetrameric uricase wherein **greater than** 90% of the uricase is in a tetrameric form, a **slightly narrower range** encompassed by the disclosed range of **at least** 90% to 100%.

Response: Applicants arguments regarding In re Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976), is considered but not found to be persuasive because of the following reasons.

In re Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976), the ranges described in the original specification included a range of '25%-60%' and specific examples of '36%' and '50%'. A corresponding new claim limitation to "at least 35%", did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside '25%-60%' range, however, a limitation to 'between '35% and 60%' did meet the description requirement.

Applicants further argue that the specification on page 17, lines 1-5, describe isolation of tetrameric uricase using ion-exchange chromatography, pooling of the fractions from the column which may be analyzed with respect to the size to determine which fraction contains substantial amounts of the tetrameric form without detectable aggregates. Of the uricase thus pooled, at least 90% may be tetrameric form; the

undesirable aggregates may thus constitute as little as about 10%, 5%, 2%, or less, of the total isolated uricase.

In the light of the varying fact patterns between In re Wertheim and the present claims, as well as Applicants own argument that the phrase "greater than 90% now encompasses a narrower range" compared to disclosed range of **at least 90%** (there being no explicit disclosure of "**at least** 90% to 100%". Similarly, claims 60-61 reciting "at least 95% or 98% of said uricase in tertrameric form lack the necessary and explicit basis in the specification and therefore remain undescribed.

The rejection is maintained for all the above reasons.

5. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-53 are rejected under 35 U.S.C. 102(b) as anticipated by Lee et al. [Science 239, 1288-1291 (1988), IDS, previously cited].

Lee et al. (1988) teach the recombinant production of full length amino acid sequence of porcine Urate oxidase (uricase) which is tetrameric and is substantially pure. Mammalian uricase is disclosed as a tetramer with subunit size of 32,000 Daltons (page 1288, column 2, first paragraph after the abstract). The reference further teaches purification to **homogeneity** of Porcine and murine urate oxidase (see, page 1289, second column). Oxidation of uric acid to allantoin is catalyzed by urate oxidase (see abstract). Increased uric acid level, due to lack of this enzyme in man can lead to gouty arthritis (page 1288, column 2).

Applicants' claims are directed to 'tetrameric mammalian uricase, wherein ~~at least about~~ greater than 90% is in tetrameric form'.

in order for a prior art reference to anticipate the claimed invention, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re

Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). Lee, when read in light of Appellants' statement of the state of the prior art as set forth in the Specification, anticipates the claimed subject matter of claim 50.

Claim 50 uses the term "greater than" in defining how much uricase must be in tetrameric form in order to be encompassed within the scope of the claim. We first look to the Specification to determine whether Appellants have acted as their own lexicographer in defining "about." See Merck & Co., v. *TEVA* Pharmaceuticals USA, Inc., 395 F.3d 1364, 1369-70, 73 USPQ2d 1641, 1646 (Fed. Cir. 2005). The review of the Specification, however, does not reveal that "greater than" has been defined in a way different from its ordinary meaning. We thus interpret "greater than" consistent with its ordinary meaning of 'more than'. We thus interpret the phrase "wherein greater than 90% of said uricase is in a tetrameric form" as encompassing a range of uricase above 90%, and thus any prior art uricase preparation that contains above 90% of the uricase in tetrameric form is encompassed by claim 50.

Lee teaches that porcine liver urate oxidase was obtained commercially and purified to homogeneity, citing footnote 8 (Lee, p. 1289). Footnote 8 states that porcine liver oxidase was obtained from Sigma, and that murine urate oxidase was purified to homogeneity using the method of Conley (1979). Conley (1979) teaches purification of uricase from mammalian tissue by precipitation under certain dialysis conditions (Conley, abstract).

Appellants assert that the Declaration of Merry R. Sherman, Ph.D, filed under 37 CFR § 1.132 and attached as Exhibit D to the Brief, supports their conclusion that "the authors of Lee would not be expected to have produced an uricase preparation in which at least about 90% of the uricase was in a tetrameric form; instead, more than 10% of the uricase would have been present in a non-tetrameric aggregated form." (Br. 12-13 (emphasis in original).) Dr. Sherman at paragraph 5 of the Declaration, referencing the Specification at page 16, lines 5-8, states that "while mammalian uricases *in vivo* (i. e., associated with the peroxisome) exist as a tetramer, isolated purified preparations of natural and recombinant uricase, as indicated in the present specification and as

disclosed by Lee, usually contain a mixture of aggregated non-tetrameric forms of the enzyme, in addition to the tetrameric form."

Page 16, lines 5-8 of the Specification, states:

Purified preparations of naturally occurring and recombinant uricases usually contain a mixture of aggregates of the enzyme, in addition to the tetrameric (140 kDa) form. The percentage of each uricase preparation that is in the tetrameric form generally varies from approximately 20% to 90%.

The Specification, as referenced by the Declaration of Dr. Sherman, thus states that uricase preparations containing up to 90% of uricase in the tetrameric form were known in the prior art. Moreover, as discussed above, claim 50 encompasses uricase preprations containing only approximately 90% of the uricase in tetrameric form. Therefore, claims 50-53 encompasses uricase preprations as prepared in the prior art, such as by Lee, and is thus anticipated by the prior art.

The reference therefore anticipates the claims.

6. Arguments in the BPAI decision:

As per the BPAI decision, affirming Examiner (See page 2 of the decision). The BPAI decision on page 3, paragraph 3 – states: "It is axiomatic that in order for a prior art reference to anticipate the claimed invention, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). We find that Lee, when read in light of Appellants' statement of the state of the prior art as set forth in the Specification, anticipates the claimed subject matter of claim 50. Because our reasoning differs from that of the Examiner, and Appellants have not had a fair opportunity to respond to the rejection, we designate our affirmance as a new ground of rejection. *See In re Kronig*, 539 F.2d 1300, 1302-03, 190 USPQ 425,426-27 (CCPA 1976).

The BPAI decision (page 5, paragraph 3 & 4) citing -

Page 16, lines 5-8 of the Specification, states:

Purified preparations of naturally occurring and recombinant uricases usually contain a mixture of aggregates of the enzyme, in addition to the tetrameric (140 kDa)

form. The percentage of each uricase preparation that is in the tetrameric form generally varies from approximately 20% to 90%.

The Specification, as referenced by the Declaration of Dr. Sherman, thus states that uricase preparations containing up to 90% of uricase in the tetrameric form were known in the prior art. Moreover, as discussed above, claim 50 encompasses uricase preparations containing only approximately 90% of the uricase in tetrameric form. Therefore, claim 50 encompasses uricase preparations as prepared in the prior art, such as by Lee, and is thus anticipated by the prior art.

CONCLUSION

In summary, we affirm the rejection of claims 50-53 as being anticipated by Lee. Because our reasoning differs from that of the Examiner, we designate the rejection as to those claims as new grounds of rejection.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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